

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE LITIGATION

THIS DOCUMENT RELATES TO  
ALL ACTIONS

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

**PLAINTIFFS' REPLY TO TRACK 1 DEFENDANTS' RESPONSE TO PLAINTIFFS'  
PROPOSED CONSOLIDATED ORDER RE: MOTION FOR CLASS CERTIFICATION**

The Track 1 Defendants' proposed class certification order and accompanying brief mischaracterizes the Court's oral rulings made at the January 19 hearing and otherwise seeks to reargue points that have already been decided against Defendants. And, despite a Court order that objections to the proposed class certification order be filed in November 2005, Defendants raise a host of new arguments, attacking, for example, the identification of "Subject Drugs," which have remained the same since the original order, and seeking to now impose residency requirements for the Class 2 or 3 representatives. For these reasons, Plaintiffs respectfully submit this short reply to Defendants' submission, tracking the organization of Defendants' brief. Redlined versions of the proposed class certification orders are also being submitted herewith.

**I. CLASS 2 SHOULD NOT BE LIMITED TO MASSACHUSETTS**

Defendants claim that Plaintiffs have not grouped state laws in a feasible manner, but Plaintiffs have. The Court's August 16, 2005 Memorandum and Order Re: Motion for Class

Certification (the “Class Order”) flatly and correctly rejected Defendants’ challenges to the certification of a multi-state class based on differing standards of scienter, reliance and proximate cause. Class Order at 55-56. The Court reaffirmed this ruling during the January 19 hearing.

*See* Hrg. Trans. at 35-36. 39.

The Court ordered Plaintiffs to provide evidence of compliance with the notice provisions of the various state consumer protection acts (Class Order at 54-55), which Plaintiffs have done (*see* Section V *infra*). The Court also noted that states should be excluded from the class definition where such states have consumer protection statutes that do not permit class actions. Plaintiffs have done this, proposing to exclude states where class actions are not permitted under the relevant consumer acts, namely Alabama, Georgia, Iowa, Kentucky, Louisiana, Mississippi and Montana.

Defendants assert that the Alaska and Virginia consumer acts should also be excluded, but they are wrong. The Virginia statute, VA. CODE ANN. §59.1-196, *et seq.*, does not prohibit class actions. Although the State of Virginia does not have a corollary to FED. R. CIV. P. 23, the Court applies federal procedural law, and not the rules of Virginia. Turning to Alaska, Defendants claimed in earlier briefing that the relevant consumer statute, ALASKA STAT. §45.50.471, *et seq.* does not authorize class actions because §45.50.531(b), which formerly pertained to class actions, had been repealed. However, ***nothing*** in the Alaska Consumer Protection Act prohibits the certification of class actions under the statute, and the repealed section to which Defendants refer merely stated that, before a class action could be filed, the plaintiff was required to submit the proposed complaint to the Attorney General and obtain his or her prior approval. *See Deadwyler v. Volkswagen of Am., Inc.*, 134 F.R.D. 128, 132 (W.D.N.C. 1991).

The remaining states are properly included in Plaintiffs' proposed Class 2, and no further grouping is necessary. Plaintiffs have carefully surveyed the statutes that they propose to include in Class 2 and have determined that class actions can be brought by and on behalf of corporations under each of them. Defendants have had ample opportunity to challenge the inclusion of the remaining state statutes into Class 2, and they have either failed to do so or, in those few instances in which they belatedly did, Plaintiffs have now addressed every criticism raised.

## **II. THE IDENTITY OF THE CLASS 1 REPRESENTATIVES DO CORRESPOND WITH THE COURT'S FINDINGS**

Defendants claim that the proposed Class 1 representatives are inconsistent with the Court's ruling at the January 19th hearing. The only specific inconsistency raised by Defendants is their proposed striking of Jane and Teresa Shepley as proposed Class 1 representatives. *See* Defendants' Proposed Order at p.2, l. c. However, the Court did not discuss the Shepleys at all. Moreover, the Shepleys' records identify that Mr. Shepley was covered by Medicare Part B, received a bill for his share of Procrit, and paid a portion thereof. *See* Haviland Decl. ¶ 35. The Shepleys are thus typical and should be permitted to represent Class 1.

## **III. CLASSES 1 AND 2 ARE OTHERWISE PROPERLY DEFINED**

In this section of their brief, Defendants first claim that the Class 1 and 2 definitions must expressly refer to reimbursements based on AWP. But Defendants fail to offer any evidence that Medicare-based reimbursements were actually based on something other than AWP, and Dr. Rosenthal and others have testified that alternate charges were never used. However, Plaintiffs will accept Defendants' proposed modification because, in practice, it does not make a substantive difference.

Defendants next argue that Class 1 should exclude individuals who have supplemental insurance, however, the Court specifically discussed and approved the inclusion of persons who made a payment or who have a currently enforceable obligation to pay. Hrg. Tr. at 61:16-20; 64:12-18. Therefore, no other changes are needed.

Defendants next propose that the time period for Classes 1 and 2 run “to December 31, 2004,” instead of “to January 1, 2005.” “To January 1, 2005” means “through December 31, 2004,” and does not include January 1, 2005, so no change is necessary.

Defendants attack the Sheet Metal Workers Health Fund as a Class 2 representative on the grounds that the Fund is not headquartered in Massachusetts. Def’s Opp. 3-4. This precise issue was discussed at the hearing (Sheet Metal paid for Part B drugs purchased and administered in Massachusetts). Hrg. Tr. at 47:1-9. After considering this argument concerning Sheet Metal’s ties to Massachusetts, the Court approved Sheet Metal as a Class representative. Hrg. Tr. at 49:12-21 (“I’m going to certify a class right now only with respect to Massachusetts, with Blue Cross and Sheet Metals as the representatives”). *See also* Hrg. Tr. 50:14-17. The Court thus already rejected Defendants’ attempt to limit the class to payors who “have their principal place of business in Massachusetts”<sup>1</sup> and logically so since payments made in Massachusetts establish the required nexus to Massachusetts law.

#### **IV. CLASS 3 REPRESENTATIVES**

The order reflects BCBS and Pipefitters as the Class 3 representatives, and Plaintiffs acquiesce to Defendants’ proposal to remove Sheet Metals as a proposed Class 3 representative (for present purposes only).

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<sup>1</sup> *See* Defendants’ Proposed Order for Class 2 and 3, submitted for the first time in this opposition.

## V. NOTICE PROVISIONS HAVE BEEN COMPLIED WITH

The Court previously ordered Plaintiffs to provide evidence of compliance with the notice provisions of the various state consumer protection acts. Class Order at 54-55. Plaintiffs subsequently provided notices as required under each of those acts and specifically pled such in the third amended complaint. *See TAMCCAC ¶¶ 643-44, 650-51.* Defendants did not object thereto but now exclaim, without any supporting argument, that the Court should not find that Plaintiffs have complied with the notice provisions. Defendants' failure to contest Plaintiffs' notices counsels in favor of the Court now finding that Plaintiffs' comprehensive notice campaign complies with the notice provisions of the various state consumer protection acts.

## VI. TOLLING

Defendants object to the tolling language that Plaintiffs proposed with respect to the Court's election not to certify either Class 2 or Class 3 beyond the State of Massachusetts.<sup>2</sup> Defendants base their objection on the assertion that the tolling laws of each state must first be analyzed before the Court can affirmatively conclude that statutes of limitation remain tolled until the Court makes a final ruling on whether to certify classes under the laws of states other than Massachusetts. Plaintiffs believe that it is likely that most states would permit such tolling. But, in any event, the Court need not conduct a state-by-state analysis of equitable tolling law at this time and instead conclude that any "denial is without prejudice and does not affect the statute of limitations in those states that permit equitable tolling, until such time as the Court makes a final ruling." Plaintiffs have made this proposed change in the accompanying orders.

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<sup>2</sup> Plaintiffs proposed that, in both versions of the proposed class certification orders, the Court rule that any denial of certification based on laws of other states be "without prejudice and does not affect the statute of limitations, which remains tolled until such time as the Court makes a final ruling." Proposed Version 1 at Part II, ¶1; Proposed Version 2 at Part II, ¶1.

## VII. SUBJECT DRUGS

The Court ordered Defendants to file an opposition to the proposed class certification order in November, 2005. Defendants did so and did not challenge the list of Subject Drugs, and the list has been unchanged since then. Nor did Defendants challenge the Subject Drugs at the January 19 hearing. Now, after all challenges are long past due, Defendants suddenly seek to eliminate drugs “consistent with the Court’s orders.” Defendants’ argument is untimely and wrong.

The list of Subject Drugs, prepared by Dr. Hartman, does include self-administered drugs. However, these are drugs covered by Part B and were identified as such by Dr. Hartman when the original order was submitted. Defendants offered no substantive objection and do not identify which drugs they claim are not Part B covered. This vague, unspecified and late challenge should be rejected. Defendants next claim that certain drugs are included for “which no liability” is found by Dr. Hartman. That matter should be the subject of a full record and summary judgment, and is not appropriate (a) at this stage, and (b) based on Defendants’ bald claim that this is so. And again, Defendants do not identify which drugs they claim fall into this category. Finally, Defendants claim that no self-administered drug should be in Class 3, yet they fail to identify which drugs should be stricken from Class 3 for this reason – yet retained within Classes 1 and 2 because they are covered by Part B. Plaintiffs do agree that self-administered drugs should not be in Class 3 and have so modified the proposed order consistent with Plaintiffs’ understanding of which Class 3 drugs are self-administered.

**VIII. SECTION 1292 CERTIFICATION IS NOT APPROPRIATE GIVEN THE PLAIN MEANING OF RULE 23(f), THE FIRST CIRCUIT'S REJECTION OF DEFENDANTS' INTERLOCUTORY APPEAL, AND THE DELAY THAT AN APPEAL WILL CAUSE IN AN ALREADY LENGTHY TRACK**

As the First Circuit has already held in this case, Rule 23(f) provides a vehicle for the court to review “unsettled legal questions.” *In re AWP*, November 25, 2005, Order, attached hereto. Rule 23(f) was enacted to allow an aggrieved party the opportunity to seek and obtain review, and it should be seen as a superior vehicle to Section 1292 with respect to appeals of class certification orders. Indeed, as the comments to Rule 23(f) indicate, review under Rule 23(f) “does not require the potentially limiting requirements of Section 1292.” Defendants should therefore proceed under Rule 23(f) and not Section 1292.

It should be obvious why Defendants’ pine for a standard other than that provided by Rule 23(f): the issues that Defendants now invoke for review have *already* been addressed by the First Circuit – and review rejected. For example, Defendants claim that the weight to be accorded expert testimony at the class certification stage is a “thorny legal issue,” Defs. Br. at 5, yet the First Circuit in its order denying the petition has already expressed “doubt” on the merits of this claim when Defendants first raised it:

Nevertheless, to avoid another petition once the district court issues a certification order, we will consider the petition on its merits now. . . . The only legal issue that defendants identify as important and unsettled is how rigorous a standard should be applied in reviewing expert methodology at the class certification stage. Even assuming that this issue is sufficiently unsettled and important to warrant immediate appellate review, which we doubt, permitting an appeal under Rule 23(f) would still be inappropriate in the absence of a showing that the issue is “likely to escape effective review if left hanging until the end of the case.” . . . In the absence of any showing that defendants here “will be forced to throw in the towel” absent an immediate appeal, *id.*, we deny the petition and “allow[] the district court an opportunity to fine-tune its class certification order,” *id.*, if necessary, as the case progresses. That approach is particularly appropriate here, where

the alleged weaknesses in plaintiffs' expert's methodology relate primarily to the individual damages phase of this case.

Defendants should follow Rule 23(f), which provides a prompt mechanism for the First Circuit to decide *if* there are issues worthy of review.

Finally, Plaintiffs do not believe that the Court should indicate its views on the desirability of an appeal. No party has briefed to this Court whether any of the issues presented are novel or worthy of review. Further, two Class representatives have died in the last few months. The delay that will surely follow if Section 1292 certification is accepted favors the deep-pocket Defendants and would deny long-awaited justice to the victims.

#### **IX. REDLINED VERSIONS OF PROPOSED CLASS CERTIFICATION ORDERS**

In order to reflect the changes to which Plaintiffs do not object (as outlined above), Plaintiffs are submitting herewith redlined versions of their proposed class certification orders.

DATED: January 26, 2006

By /s/ Steve W. Berman

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**CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE**

Docket No. MDL 1456

I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on January 26, 2006, I caused copies of **PLAINTIFFS' REPLY TO TRACK 1 DEFENDANTS' RESPONSE TO PLAINTIFFS' PROPOSED CONSOLIDATED ORDER RE: MOTION FOR CLASS CERTIFICATION** to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman

Steve W. Berman

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## General Docket

### US Court of Appeals for the First Circuit

Court of Appeals Docket #: 05-8008

Filed: 8/31/05

Nsuit: 0 (Criminal or NOT SET)

IN RE: Pharamaceutic, et al v.

Appeal from: U.S. District Court of MA

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Lower court information:

District: 0101-1 : 01-12257

Ordering Judge: Patti B. Saris, Judge

trial judge: Marianne B. Bowler, Magistrate Judge

court reporter: Marie L. Cloonan, Court Reporter

court reporter: Debra M. Joyce, Court Reporter

court reporter: Valerie O'Hara, Court Reporter

court reporter: Cheryl Dahlstrom, Court Reporter

court reporter: Carol Lynn Scott, Court Reporter

court reporter: Teri Celeste Gibson, Court Reporter

court reporter: Judith A. Twomey, Court Reporter

court reporter: ECR

Date Filed: 8/16/05

Date order/judgment: 8/16/05

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Fee status: waived

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Prior cases:

None

Current cases:

None

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Panel Assignment:

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05-8008 IN RE: Pharamaceutic, et al v.

11/25/05

JUDGMENT entered by Judge Kermit V. Lipez, Chief Judge Hector M. Laffitte, Judge Mary M. Lisi. This is a petition for leave to appeal from the district court's grant of class certification. We deny the petition because it is premature in that no class certification order has yet issued and, even if it had, this petition does not present an unsettled and important legal issue that is likely to escape effective review if an interlocutory appeal is not permitted. DISCUSSION Rule 23(f) of the Federal Rules of Civil Procedure allows a party to apply for leave to file an interlocutory appeal from an order granting or denying class certification if application is made to the court of appeals "within ten days after entry of the order" (emphasis added). Here, although the district court expressed its intention to enter an order certifying a class, no such order has yet entered. Accordingly, this petition is premature and could be dismissed on that ground alone. That is especially true of the district court's qualified intention to certify a nationwide class of Medicare Part B beneficiaries. The district court expressly deferred ruling on plaintiffs' motion to certify such a class pending plaintiffs' motion to add individual class representatives. Even if plaintiffs amend their complaint to add such class representatives, the court indicated that such a class would be certified only if the purported class representatives are found to be "adequate" after an opportunity for further discovery and briefing by opposing parties. Nevertheless, to avoid another petition once the district court issues a certification order, we will consider the petition on its merits now. Rule 23(f) gives this court "unfettered discretion" whether to permit an interlocutory appeal from the grant or denial of class certification. Fed. R. Civ. P. 23(f) advisory committee's note. That discretion is guided, however, by the dual purposes of the rule--to "provide a mechanism through which appellate courts, in the interests of fairness, can restore equilibrium when a doubtful class certification ruling would virtually compel a party to abandon a potentially meritorious defense," Waste Mgmt. Holdings, Inc. v. Mowbray, 208 F.3d 288, 293 (1st Cir. 2000), and to "furnish[] an avenue, if the need is sufficiently acute,

whereby the court of appeals can take earlier-than-usual cognizance of important, unsettled legal questions, thus contributing to both the orderly progress of complex litigation and the orderly development of the law," id. To avoid encouraging too many fruitless Rule 23(f) applications, however, we have restricted the second avenue for appeal "to those instances in which an appeal will permit the resolution of an unsettled legal issue that is important to the particular litigation as well as important in itself and likely to escape effective review if left hanging until the end of the case." Id. We have further indicated that we would "exercise our discretion judiciously," id., and "err, if at all, on the side of

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05-8008 IN RE: Pharamaceutic, et al v.

allowing the district court an opportunity to fine-tune its class certification order, rather than opening the door too widely to interlocutory appellate review," id. (citation omitted). Under those standards, the present petition fails. The only legal issue that defendants identify as important and unsettled is how rigorous a standard should be applied in reviewing expert methodology at the class certification stage. Even assuming that this issue is sufficiently unsettled and important to warrant immediate appellate review, which we doubt, permitting an appeal under Rule 23(f) would still be inappropriate in the absence of a showing that the issue is "likely to escape effective review if left hanging until the end of the case." Id. Here, defendants, large drug companies, do not claim that the intended certification order would force them to settle the case. Cf. id. at 294-95 (noting that "what might be 'ruinous' to a company of modest size might be merely unpleasant to a behemoth"). Rather, in an attempt to show that an immediate appeal is necessary, defendants state only that the issue may escape end-of-case review "because class actions often settle prior to final judgment." If that rationale--which applies to all class actions--were sufficient to satisfy the requirement that end-of-case review be shown insufficient, that requirement would be effectively nullified and our concern about "opening the door too widely to interlocutory appellate review," Mowbray, 208 F.3d at 294, would be realized. In the absence of any showing that defendants here "will be forced to throw in the towel" absent an immediate appeal, id., we deny the petition and "allow[] the district court an opportunity to fine-tune its class certification order," id., if necessary, as the case progresses. That approach is

particularly appropriate here, where the alleged weaknesses in plaintiffs' expert's methodology relate primarily to the individual damages phase of this case. The district court recognized that the methodology may not work for the individual damages phase but concluded that such an eventuality did not preclude class certification for purposes of determining liability and aggregate damages. Rather, as the district court recognized, if there is a need for individual proceedings on damages, the court could decertify the class at that time. See Fed. R. Civ. P. 23(c)(4)(A); see also Tardiff v. Knox County, 365 F.3d 1, 6-7 (1st Cir. 2004) (approving that approach); Smilow v. Southwestern Bell Mobile Sys., 323 F.3d 32, 39-41 (1st Cir. 2003) (same); Mowbray, 208 F.3d at 297 n.6 (same). The petition for leave to appeal is denied. [1062853-1] [05-8008] (mlyn)

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